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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,175	10/31/2003	John R. Bianchi	4002-3441	1020

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EXAMINER

GBERBI, SUZETTE JAIME J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/699,175

Applicant(s)

BIANCHI ET AL.

Examiner

Suzette J Gherbi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72-134 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72-134 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment dated 12/17/04 has been received in application serial number 10/699,175.

Specification

2. The amendment filed 12/17/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "Each of dowels 500 are illustrated as having a width less than approximately one-half of the width of the adjacent vertebral body. Applicant is referred to MPEP 2125 which states:

PROPORTIONS OF FEATURES IN A DRAWING ARE NOT EVIDENCE OF
ACTUAL PROPORTIONS WHEN DRAWINGS ARE NOT TO SCALE

When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value. See *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000) (The disclosure gave no indication that the drawings were drawn to scale. "[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue."). However, the description of the article pictured can be relied on, in combination with the drawings, for what they would reasonably teach one of ordinary skill in the art. In re Wright, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977) ("We disagree with the Solicitor's conclusion, reached by a comparison of the relative dimensions of appellant's and Bauer's drawing figures, that Bauer clearly points to the use of a chime length of roughly 1/2 to 1 inch for a whiskey barrel.' This ignores the fact that Bauer does not disclose that his drawings are to scale. ... However, we agree with the Solicitor that Bauer's teaching that whiskey losses are influenced by the distance the liquor needs to traverse the pores of the wood' (albeit in reference to the thickness of the barrelhead)" would have suggested the desirability of an increased chime length to one of ordinary skill in the art bent on further reducing whiskey

losses." 569 F.2d at 1127, 193 USPQ at 335-36.)

Applicant is therefore required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 72-134 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular in claims 72, 91 and 111 applicant claims the limitations of "...said upper and lower portions being non-arcuate along at least a portion of the length of the implant....". The opposed upper and lower surfaces of applicants implants are not non-arcuate. If one were to dissected the invention in half and look at the side as a whole there would be a portion that is "arcuate". The term arcuate has not been defined by applicants specification therefore it is given is broadest dictionary definition. Applicant is encouraged to utilized the terminology in there specification which is "flattened" which is differently defined that non-arcuate.

Applicant further claims a range of “....*less than approximately one-half of the width of the adjacent vertebral bodies*” and this range constitutes new matter.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 72, 91 and 111 are rejected under 35 U.S.C. 102(e) as being anticipated by Pafford et al. 6,371,988. Pafford et al. discloses the invention *as claimed noting figures 7, 24 and 47-49 and as best interpreted* comprising:

An interbody spinal implant (40) made of cortical bone (col. 6, lines 43-48) for insertion at least in part into an implantation space formed across the height of a disc space between adjacent vertebral bodies of a human spine, the vertebral bodies having an anterior aspect and a posterior aspect comprising:

a leading end (48) , a trailing end (26') opposite the leading end, wherein the implant has a length along a mid-longitudinal axis of said implant from the leading end to the trailing end; opposed upper and lower portions (*the upper portion is the tooled beveled space shown in figures 47-49 and the lower is interpreted as opposite of the beveled*

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end) between the leading and trailing ends said upper and lower portion being non-arcuate along at least a portion of the length of the implant (**see col. 7, lines 64-65 which discloses that the crest 44 of each tooth 43 is flat**); an interior facing side, an exterior facing side opposite the interior side, and a maximum width there between capable of being less than approximately one-half of the width of the adjacent vertebral bodies (see fig. 24 interior side is right and exterior side is left); said interior and exterior sides connecting the upper and lower portions and said leading and trailing end, said leading end having a generally straight portion (straight slot including hole 49 for tool) from side to side, said interior side (*see fig. 24 where interior side of one of the implants is to the right*) forming a corner (*the tooled bevel side and the straight slot for the tool form this corner*) with said generally straight portion of the leading end; said implant being manufactured from a bone ring obtained from a major long bone of a human having a medullary canal.

Response to Arguments

7. Applicant's arguments filed 12/17/04 have been fully considered but they are not persuasive. Applicant has amended the specification and contends that Pafford et al. does not teach "upper and lower portions being non-arcuate along at least a portion of the length of the implant"and "a maximum width there between, wherein the maximum width of the implant is less than approximately one-half o the width of the adjacent vertebral bodies. As discussed above in paragraph 2 applicants drawing are

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not to scale and the claimed ranges are not supported by the figures (also see MPEP

2163 which states:

When an explicit limitation in a claim "is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation." Hyatt v. Boone, 146 F.3d 1348, 1353, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998). See also In re Wright, 866 F.2d 422, 425, 9 USPQ2d 1649, 1651 (Fed. Cir. 1989).

8. The drawings are inconclusive with regards to a width less than approximately one-half of the width of the adjacent vertebral body. With regards to the argument that Pafford et al. does not disclose a "non-arcuate" portion along at least a portion of the length of the implant, as noted in paragraph 3 Pafford et al. does disclose this limitation by the flat or flattened or non-arcuate cross "44".

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

10. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

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11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

A handwritten signature in black ink, appearing to read 'Suzette J-J Gherbi', written in a cursive style.

Suzette J-J Gherbi
08 March 2005